

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008]

## PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

### § 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use*. Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155–92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor*. See No. 042976 in § 510.600 of this chapter.

(c) *Limitations*. Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

## PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.

529.56 Amikacin.

529.400 Chlorhexidine tablets and suspension.

529.536 Detomidine.

529.1030 Formalin.

529.1044 Gentamicin sulfate in certain other dosage forms.

529.1044a Gentamicin sulfate intrauterine solution.

529.1044b Gentamicin sulfate solution.

529.1115 Halothane.

529.1150 Hydrogen peroxide.

529.1186 Isoflurane.

529.1350 Meloxicam.

529.1660 Oxytetracycline.

529.1940 Progesterone intravaginal inserts.

529.2150 Sevoflurane.

529.2464 Ticarcillin powder.

529.2503 Tricaine methanesulfonate.

529.2620 Triptorelin.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

### § 529.40 Albuterol.

(a) *Specifications*. A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals*. See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount*. Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use*. For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.